

**REQUEST FOR APPLICATIONS FOR PROJECTS TO
PROMOTE EVIDENCE BASED PRESCRIBING NATIONWIDE:**

(EITHER OR BOTH ITEM 1 AND ITEM 2 BELOW)

- 1. National projects aimed at educating current prescribers about the impact of pharmaceutical industry drug promotion and marketing;**
- 2. National projects that establish protocols and procedures at academic medical centers and teaching hospitals to train prescribers-in-training in evidence based prescribing practices; that educate administrators, staff, and prescribers-in-training about pharmaceutical promotion and marketing practices; and that foster a conflict of interest free medical education environment.**

Deadline for Physical Receipt of Grant Applications:

**EXTENDED TO JUNE 3, 2010
5:00 PM (Pacific Time)**

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Request for Applications

The Consumer and Prescriber Education Program is now soliciting grant applications for either or both item 1 and item 2 below:

1. National projects aimed at educating current prescribers about the impact of pharmaceutical industry drug promotion and marketing;
2. National projects that establish protocols and procedures at academic medical centers and teaching hospitals to train prescribers-in-training in evidence based prescribing practices; that educate administrators, staff, and prescribers-in-training about pharmaceutical promotion and marketing practices; and that foster a conflict of interest free medical education environment.

The grants will be made as part of the settlement of *In the Matter of Warner Lambert Company, LLC* (Case No. 04C14403).

Background - The Consumer and Prescriber Education Program

On May 13, 2004, Warner-Lambert, a division of Pfizer, Inc., entered into an Assurance of Voluntary Compliance/Discontinuance with the Attorneys General of 50 States and the District of Columbia to settle allegations that Warner-Lambert conducted an unlawful marketing campaign for the drug Neurontin that violated state consumer protection laws. Among other things, the settlement provided for a \$21 million Consumer and Prescriber Education Grant Program to be administered by the Special Committee of State Attorneys General pursuant to an Oregon Court Order Governing the Administration of Multistate Grant and Advertising Program (See <http://www.consumerprescribergrantprogram.org> for the Assurance and Court Order referred to.) and an Attorney General Memorandum of Understanding.

The Special Committee is comprised of six permanent members (the Attorneys General of Florida, New York, Ohio, Oregon, Texas, and Vermont) and two rotating members (currently the Attorneys General of Illinois and Massachusetts).

The Oregon Court Order provides that,

“Distributions from the Prescriber and Consumer Education Subaccount may be approved, and distributions used, only for the purpose of funding programs designed to educate prescribers

and/or consumers relating to drug information, drug marketing, and the conditions for which drugs are prescribed..." (Order Governing the Administration of Multistate Grant and Advertising Program, Section 2.6.)

This is the third round of grantmaking for the program. The first and second rounds funded grants to provide prescribers and consumers with information related to prescription drugs, focusing on the way drugs are marketed and the appropriate ways they should be prescribed. Twenty-nine grants were made nationwide, totaling over \$15 million. As in prior rounds, grants will be awarded following an application, due diligence and Special Committee approval process.

The Special Committee has hired Harry Snyder, based in San Francisco, California, to conduct the application and due diligence process and assist the Special Committee in the approval and administration of grants.

Goal

The goal of this round of grants is to increase evidence based prescribing nationwide by educating current prescribers and prescribers-in-training about the impact of pharmaceutical industry promotion and marketing practices (e.g., gifts and gratuities, "detailing", professional association sponsorships, presence in patient care facilities, undisclosed support of research, presentations, and publications, etc.)¹ The following examples illustrate the potential kinds of projects that might be funded in this round.

¹ Projects funded in previous rounds by the Consumer and Prescriber Education Program have identified a number of pharmaceutical industry marketing and promotion practices that can unduly influence prescribing decisions. Some of these practices include giving of gifts, gratuities and drug samples to prescribers, reimbursement of travel and continuing education expenses, on-site access, and visits by drug company representatives. In addition, in April 2009, the Institute of Medicine's Committee on Conflict of Interest in Medical Research, Education, and Practice (hereafter "Committee") issued an extensive report on this topic. The report states:

"Patients and the public benefit when physicians and researchers collaborate with pharmaceutical, medical device, and biotechnology companies to develop products that benefit individual and public health. At the same time, concerns are growing that wide-ranging financial ties to industry may unduly influence professional judgments involving the primary interests and goals of medicine. Such conflicts of interest threaten the integrity of scientific investigations, the objectivity of professional education, the quality of patient care, and the public's trust in medicine." (Bernard Lo and Marilyn J. Field, Editors, *Conflict of Interest in Medical Research, Education, and Practice*, Institute of Medicine, Board on Health Sciences Policy, Committee on Conflicts of Interest in Medical Research,

Attorney General Consumer and Prescriber Education Program

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1. National projects aimed at educating current prescribers about the impact of pharmaceutical industry drug promotion and marketing by:

- Offering continuing education credit, focused on drug industry practices and their influence on prescribing, health outcomes and health economics;
- Educating prescribers about methods to access and use readily available sources of comparative effectiveness research;
- Advancing the use of information technology for safe, evidence based prescribing; and
- Educating prescribers about the potential for conflicts of interest, impact on prescribing, and ethical problems that can result from pharmaceutical industry gratuities, professional association sponsorship, presence in patient care facilities, undisclosed support of research, presentations and publication, “detailing”, etc., leading to the adoption and implementation by prescribers of policies eliminating or restricting such practices.

2. National projects that establish protocols and procedures at academic medical centers and teaching hospitals to train prescribers-in-training in evidence based prescribing practices; that educate administrators, staff, and prescribers-in-training about pharmaceutical promotion and marketing practices; and that foster a conflict of interest free medical education environment by:

- Educating academic medical center and teaching hospital staff and administrators about the need for educating prescribers-in-training regarding conflicts of interest and the impact on prescribing and professional norms and ethical standards that can result from future prescribers exposure to pharmaceutical industry gratuities, professional association sponsorship, presence in patient care facilities, undisclosed support of research, presentations and publication, “detailing”, etc., at such institutions;

Education, and Practice, April 2009, p. 1.)
(Footnote 1 continued) The Committee’s report identifies a number of conflicts of interest from pharmaceutical industry promotion and marketing practices in medical education, medical practice, biomedical research, development of clinical practice guidelines and institutional conflicts.

- Educating academic medical center and teaching hospital staff, administrators and prescribers-in-training that the impact of pharmaceutical industry gratuities, professional association sponsorship, presence in patient care facilities, undisclosed support of research, presentations and publication, “detailing”, etc., can conflict with norms and standards for professional, conflict of interest free medical care;
- The adoption of institutional policies at academic medical centers and teaching hospitals aimed at eliminating or limiting prescriber-in-training exposure to pharmaceutical industry gratuities, professional association sponsorship, presence in patient care facilities, undisclosed support of research, presentations and publication, “detailing”, etc., at such institutions;
- Encouraging the adoption by academic medical centers and teaching hospitals of protocols, rules or regulations that eliminate or restrict inappropriate pharmaceutical industry gifts, gratuities, sponsorships, payments, travel or other reimbursements, payment for lectures or presentations, etc. and other drug promotion and marketing activities that may create prescribing conflicts; and
- Resulting in institutionalizing teaching curricula at academic medical centers and teaching hospitals that provide prescribers-in-training with the knowledge and critical skills necessary to evaluate prescription drug information and industry marketing techniques.

The above examples are not intended to limit other, innovative approaches to achieve the goals stated above.

Geographic Reach

The Special Committee is interested in receiving proposals that will be national in reach, for example, nationwide projects and projects that impact large geographic and population areas of the United States and that can be combined with other projects to achieve national coverage.

Applicants are encouraged to seek out collaborators around the country in order to reach as many regions as possible. Where appropriate to achieve national scope, partnership projects of different agencies or institutions are encouraged. Although it is not a requirement, proposals that include commitments from other sources of matching funding, supplemental funding, and/or other resources, for the purpose of funding a project of national coverage or reaching as many geographic or population areas as possible are encouraged.

Project Evaluation

Applications must include a proposed evaluation plan for periodic and final evaluation of the project outcomes, how and if goals have been met and the effectiveness of the project work. The application should describe in detail how the outcomes of the project will be evaluated, whether numeric or other measures of project achievements are contemplated, and if evaluation will be done internally or by an external provider. Evaluation of the project's effect on actual prescribing is encouraged and applicants are encouraged to collaborate with organizations with access to prescribing data. The Special Committee is also interested in projects that evaluate changes in patient outcomes.

While grant funds can be used for evaluating projects funded in this round of grants, funding is not available for projects to conduct scientific, medical, clinical or academic research or for general operating support.

Grants Budget and Project Duration

The Special Committee intends to award up to \$12,000,000 in this round of grant making. At this time, the Special Committee anticipates that it will make up to six grants ranging from \$500,000 to \$12,000,000. The precise number and dollar amount for grants will be determined at the time grants are awarded. The Special Committee anticipates that this will be the final round of grant making for this program.

The duration of the projects should not exceed 36 months.

Grants will only be made to fund activities that have not been previously funded or that, but for the receipt of the grant, would not be fully funded. Projects to expand the implementation of a project previously funded by the Consumer and Prescriber Education Program will be considered. Grant funds must not be used to supplant or replace any existing or budgeted funds for any program, purchase or activity. Other sources of funding may not be reduced because of a grant award from the Consumer and Prescriber Education Program.

Eligibility

Funding under the Consumer and Prescriber Education Program is limited to:

- Academic institutions
- Nonprofit organizations with current 501(c)(3) status with expertise and experience in health-related or consumer protection issues
- Government agencies
- Collaborations of any of the above

A letter supporting their request from the State Attorney General of the state in which the entity operates must accompany applications by nonprofit organizations.

Selection Criteria

The Oregon Court Order states:

“The Special Committee shall give special consideration to programs that (i) relate to medical and psychological conditions for which Neurontin was prescribed and/or to classes of drugs used to treat these conditions; (ii) can demonstrate through objective criteria that their proposal is likely to have a measurable impact on prescribers’ access to relevant information about drugs prescribed or on the health and/or welfare of consumers; (iii) provide national and regional benefits as opposed to programs that benefit individual states.” (Order Governing the Administration of Multistate Grant and Advertising Program, Section 2.7.)

The Order also states that in deciding on requests for funding the Special Committee may consider the following factors and others, which the Special Committee deems relevant:

- a. The intended purpose of the grant;
- b. Competing requests for grant funding;
- c. The financial ability of the intended grant recipient to obtain the requested goods, services or funding without grant funds;
- d. The anticipated public benefit to be served by approving the grant;
- e. The ability of the Special Committee to audit the use of the grant to ensure that the grant is used solely for purposes authorized hereunder;

- f. The amount of previous grants made to a particular grant recipient and the use of previous grants in accordance with the terms of the Assurance and Order;
- g. The ability of the grant recipient to provide the Special Committee with a report regarding the actual results obtained as a result of any grant; and
- h. The academic institution or not-for-profit entity (or its principals if the entity has not existed for three years) has previously successfully operated programs eligible for funding by the Consumer and Prescriber Education Program.

In addition to the factors listed above, consideration will be given to the following:

1. National projects aimed at educating current prescribers about the impact of pharmaceutical industry drug promotion and marketing:

- The degree to which the project will achieve measurable benchmarks during the project and measurable outcomes at the conclusion of the project for educating prescribers about such impact;
- The degree to which the project will have a measurable impact on increasing evidence based prescribing by current prescribers.

2. National projects that establish protocols and procedures at academic medical centers and teaching hospitals to train prescribers-in-training in evidence based prescribing practices; that educate administrators, staff, and prescribers-in-training about pharmaceutical promotion and marketing practices; and that foster a conflict of interest free medical education environment:

- The degree to which the project will achieve measurable benchmarks during the course of the project and measurable outcomes at the conclusion of the project for educating future prescribers about pharmaceutical industry promotion and marketing practices and the impact such practices can have on prescribing behavior;
- The degree to which the project will have measurable outcomes on the attitudes and knowledge of prescribers-in-training regarding the impact of pharmaceutical industry promotion and marketing;
- The degree to which the project will have a measurable impact on increasing evidence based prescribing practices through educating prescribers-in-training, primarily residents;
- The degree to which the project will have a measurable impact on implementing institution wide commitments by academic medical centers

and teaching hospitals to a learning and practice environment free of conflicts of interest.

3. Criteria for All Projects

- The degree to which the project will advance the purposes of the Oregon Court Order and the Consumer and Prescriber Education Program;
- The ability of the project to be sustained in the absence of additional Consumer and Prescriber Education Program grant funding;
- The degree to which the project will have an impact on prescribers and academic medical centers and teaching hospitals nationally or over a broad geographic or population area of the country;
- The degree to which the proposed budget is appropriate, reasonable and cost effective in carrying out the proposed activities;
- The qualifications of the applicant, key personnel and partners and degree to which they have demonstrated the capacity to successfully implement the project, including the ability to change behaviors.

It is possible no grants will be made if the Special Committee determines that no applications satisfy the criteria and requirements in this request. The Special Committee is the final decision-maker on all substantive questions. There is no appeal process.

Additional Requirements

Successful applicants will also be required to satisfy the following conditions:

- Execute a grant contract setting forth the terms and conditions of the grant, including payment and use of grant funds, reporting on the progress of the project and on the expenditures of grant funds and recordkeeping requirements;
- Comply with any written condition(s) that the Special Committee has attached to the grant;
- Submit quarterly progress and financial reports and a final report on the use of the funds and the goals achieved to the Special Committee; and

- Certify, at the end of the grant period, that the grantee has complied with the contractual provisions described in Section 2.17 of the Oregon Court Order.²

Grants are not final and no expenses should be incurred until a Grant Contract between the applicant and the State of Oregon acting by and through its Department of Justice has been fully executed.

Grant Application Instructions

To apply for funds, complete the Grant Application and **deliver five copies** (four (4) hardcopies and one (1) electronic copy in PDF format on CD ROM) **on or before 5:00 PM (Pacific Time), June 3, 2010 to:**

Attorney General Consumer and Prescriber Education Program
C/o Grant Administrator: Harry Snyder
1008 General Kennedy Avenue, 2nd Floor, Suite B
San Francisco, CA 94129
T: 415.561.6747
F: 415.561-6746
E: cypresfunds@sbcglobal.net
W: www.cypresfunds.net

E-mail submissions will not be accepted.

All Grant Applications must be physically received by 5:00 PM (Pacific Time), **June 3, 2010**. If you do not receive an acknowledgement of receipt within five business days of submitting your Grant Application, please contact Tanecia Echols at [415] 561-6747.

² Section 2.17 of the Oregon Court Order states: “ The Special Committee shall require in any contract with a grantee of the Consumer Prescriber and Education Program that the grantee possesses, with respect to any representation made in a public communication produced in connection with said grant, substantial evidence or substantial clinical experience that substantiates the representation.”

Format

Applications should be no more than twenty (20) pages in length (not including the Cover Page and Attachments) and should be double-spaced. Please use a 12-point font and one inch margins on all sides of the pages. Each page of the document and attachments should indicate the name of the principal applicant and the page number. Please make sure one of the four (4) hard copies of the application and attachments is included in a 3-hole ring binder and the one (1) electronic copy of the application and attachments is in PDF format only.

Cover Page and Cover Letter

Please include a Cover Page using the form Appendix A, making sure to complete all requested fields. In addition, please include a letter signed by the president, executive director, or dean of your organization, department, or school acknowledging awareness and support of the application.

Application Components

Applications must provide all of the following information and must be formatted with sections numbered and subtitled to correspond to the order below:

- 1 ☐ Goals and objectives (1 pg maximum)
- 2 ☐ Impact and significance (2 pgs maximum)
- 3 ☐ Problem Statement (2 pgs maximum)
- 4 ☐ Proposed Methods (10 pgs, to include a description of the methods proposed to address the problem(s), the geographic reach of the project, number and nature of prescribers and/or prescribers-in-training to be reached, results expected, and sustainability of the project at the end of the grant)
- 5 ☐ Anticipated barriers/challenges and strategies for each (3 pgs maximum)
- 6 ☐ Proposed evaluation plan (2 pgs)

Attachments

Essential additional information and supporting documents should be attached to the application. **However, please keep the length of attachments to a minimum.**

Please provide the following attachments on separate pages to correspond to the order below:

- A ☐ Description of applicant (including mission and summary of accomplishments for the past year; if part of a larger organization, please be specific to your department or program). If multiple entities are involved, the application should designate a lead applicant that will be responsible for the overall project, identify and describe the other entities to be involved in the project, describe the management structure for the project, identify the mechanisms (contract, memorandum of understanding, etc.) to be employed to assure accountability in project activities and deliverables, and describe the extent to which the entities have collaborated on projects in the past and results of such projects.
- B ☐ Itemized project budget (See forms-Appendices B1, B2, & B3)³.
- C ☐ Two letters of reference (one from within the organization, one from outside).
- D ☐ Brief biographies of key project and organizational staff, including a summary of qualifications and responsibilities. Describe the Principal Investigator/Project Director's experience managing a project of this size. (one paragraph, not to exceed 1/3rd of a page per person).
- E ☐ List of Board of Directors or Advisors (including board position and organizational affiliation), if applicable.
- F ☐ Examples of your similar past projects and examples of your success at changing behavior of prescribing professionals.

³ Indirect Costs must not exceed 10% of Total Direct Costs.

- G ☐ If a 501(c) 3 organization, your organization's (1) IRS determination letter, (2) Two most recent Form 990s, (3) Two most recent, completed full-year financial statements (expenses, revenues and balance sheet) audited if available, and (4) Current annual operating budget.
- H ☐ If a 501(c) 3 organization, a letter of support from your State's Attorney General or other authorized party (See sample letter Appendix C.) If you are an accredited academic institution or a governmental entity, no letter of support from a State Attorney General's Office is necessary.
- I ☐ A Detailed Work Plan describing in detail the tasks and activities to be undertaken in order to accomplish the proposed project.
- J ☐ A Proposed Timeline indicating (by quarter) the sequence and duration of the activities to be conducted, as well as the expected benefits to result, and key benchmarks/milestones/deliverables for the project.
- K ☐ A Conflict of Interest Declaration by the Applicant Institution. (Appendix D.)
- L ☐ A Conflict of Interest Declaration by the Principal Investigator/Project Director and other key personnel (0.5 FTE or greater). (Appendix E.)
- M. ☐ Bibliography.

Contact Information

The Special Committee's Grant Administrator welcomes phone calls and e-mails from applicants to clarify the application guidelines and procedures. If any request for clarification, or any other factor, results in a material change in any provision of this Request for Applications the Grant Administrator will post an Addenda to the website listed below. Applicants are responsible for checking the website listed below to determine whether an Addenda has been issued. Staff will not pre-evaluate proposed projects. Calls or e-mails to discuss the details of pending applications or to schedule meetings are strongly discouraged.

For questions, please contact:

Attorney General Consumer and Prescriber Education Grant Program
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